

REMARKS

Applicants have received and carefully reviewed the Advisory Action mailed April 11, 2003. With the above amendments, claims 1-9, 11-15 and 21 are pending, and claims 24-31 are newly presented. Reexamination and reconsideration are respectfully requested.

Applicants note that several pending claims were subject to a restriction requirement and have been withdrawn from consideration. Applicants request that, if a generic claim is allowed, these withdrawn claims be reinstated.

In the Final Action, and again in the Advisory Action, the Examiner has stated a rejection of all claims under 35 U.S.C. §102(e) as being anticipated by Heck, U.S. Patent No. 6,083,207. The central question has been whether Heck discloses a device including a compressible valve sleeve. The Examiner asserts that Heck does disclose a compressible element, while Applicants respectfully disagree.

The Examiner has stated that pinching of the element 300 is required in the Heck device in order for the device to prevent leakage of blood as disclosed in the Heck specification. Element 300 appears to be passed through the hemostatic valve of Heck, and is described by Heck as a dilator at column 9, lines 12-20. At least for the reasons given below, Applicants believe that the fact that element 300 is passed through the hemostatic valve of Heck by itself demonstrates that the element 300 is not supposed to be compressed or pinched. Applicants further believe that because element 300 includes a proximal hub, there would be no reason to expect or interpret Heck as disclosing that element 300 must or needs to be compressed to prevent blood outflow.

Heck cites sources which specifically teach not pinching a device that is passed through a hemostasis valve. Heck cites several conventional hemostasis valves as including those of U.S. Patent Nos. 5,092,857 and 4,909,798 at column 1, lines 25-29. U.S. Patent No. 5,092,857 notes the following:

Thus, it is important in providing a sealing mechanism for a hemostasis valve unit such that the unit:

1. is universal, i.e., useful with both guidewires and with catheters having a wide range of diameters;
2. provides relatively easy insertion and withdrawal of all diameters of catheters;
3. is free from excessive restriction which would cause hemodynamic dampening; and

4. has sufficient strength not to collapse on the insertion and removal of the various medical devices during the introduction of catheters into blood vessels.

U.S. Patent No. 5,092,857 at column 2, line 67 to column 3, line 10 (emphasis added).

Hemodynamic dampening is described in the following paragraph:

Another problem shown by many prior art hemostasis cannulas is that the cardiologist must be able to "feel" the catheter as it is inserted through the gaskets or other sealing members of the hemostasis valve and ultimately into a blood vessel. If insertion of the catheter through the hemostasis valve is too difficult, the cannula unit may be rejected by cardiologists as being difficult to use during catheter insertion. Concomitantly, the use of hemostasis valves which exert undue pressure on the side walls of inserted catheters may lead to excessive hemodynamic dampening of the catheter. In other words, excessive pressure on the exterior side-walls of a catheter may cause a narrowing of the catheter's diameter thereby altering measurement parameters within the catheter.

U.S. Patent No. 5,092,857 at column 2, lines 42-56 (emphasis added). The references cited by Heck with respect to hemostasis valves explicitly disclose that it is undesirable to pinch a catheter inserted through a hemostasis valve.

Applicants note that element 300 includes a proximal hub as illustrated in Figs. 1-2. In light of the proximal hub on element 300, there is no basis for suggesting that element 300 must be pinched to prevent blood leakage through element 300, as the Examiner asserts. Hubs are generally known in the catheter arts as including or readily coupling to non-return valves taking a variety of forms which prevent fluid leakage. It appears to Applicants that a problem of blood leaking from the proximal end of element 300 does not exist, since element 300 is shown to include a hub.

Applicants again note that Heck teaches the use of a pliant material for the partitioned hemostasis valve 14, for example at column 5, lines 53-59. This is in accordance with the teachings cited by Heck. Heck has no reason to pinch element 300, because it has a hub at its proximal end, preventing blood leakage. Further, Heck cites patents which explicitly teach that one typically avoids pinching an element passed through a hemostasis valve.

In light of the above, Heck does not disclose means for compressing a valve sleeve as recited in claim 1. Instead, the Examiner is reading this recitation from the claim into the cited reference and modifying that taught by the reference to match the claim. Such a modification is entirely impermissible under §102(e), which requires actual disclosure of each and every element

of the claim. Therefore, Applicants believe that independent claims 1, 3, 12 and 15, which all recite means for compressing a valve sleeve, along with their dependent claims 2, 4-9, 11, 13, 14 and 21, are clearly patentable over the cited reference.

Applicants have added newly presented claims 24-31. It is believed that these newly presented claims are in condition for allowance and include features which clearly distinguish over Heck.

Newly presented independent claim 24 recites a valve mechanism for attachment to an introducer sheath, the valve mechanism comprising a sheath receiver at a distal end of the valve mechanism, the sheath receiver adapted to receive the proximal end of an introducer sheath and a pinch member having an open configuration and a closed configuration, the pinch member sized to receive a compressible valve sleeve. The sheath receiver and the pinch member of claim 24 are placed such that when a compressible valve sleeve having a lumen is received by the pinch member and an introducer sheath having a lumen is received by the sheath receiver, fluid communication is created from the introducer sheath lumen into the compressible valve sleeve lumen.

Newly presented claim 25 depends from claim 24 and further recites that when a compressible valve sleeve is received by the pinch member and the pinch member is in the closed configuration, fluid flow through the compressible valve sleeve is substantially prevented. Newly presented claim 26 also depends from claim 24 and recites that when a compressible valve sleeve with a guidewire inserted therethrough is received by the pinch member and the pinch member is in the closed configuration, fluid flow through the compressible valve sleeve is substantially prevented. Newly presented claim 27 depends from claim 24 and recites that the valve mechanism further comprises a valve sleeve seat for receiving a distal end of a compressible valve sleeve, wherein the valve sleeve seat is located between the pinch member and the sheath receiver.

Newly presented independent claim 28 recites a valve system for attachment to an introducer sheath, the valve system comprising a compressible valve sleeve having a proximal end, a distal end, and a lumen therethrough, and a valve mechanism including a sheath receiver adapted to receive the proximal end of an introducer sheath and a pinch member having an open configuration and a closed configuration and sized to receive the compressible valve sleeve. For the valve system of claim 28, the sheath receiver and the pinch member are placed such that

when the compressible valve sleeve is received by the pinch member and an introducer sheath having a lumen is received by the sheath receiver, fluid communication is created from the introducer sheath lumen into the compressible valve sleeve lumen.

Newly presented claim 29 depends from claim 28 and recites that when the compressible valve sleeve is received by the pinch member and the pinch member is in the closed configuration, fluid flow through the compressible valve sleeve is substantially prevented. Newly presented claim 30 also depends from claim 28 and recites that when the compressible valve sleeve with a guidewire inserted therethrough is received by the pinch member and the pinch member is in the closed configuration, fluid flow through the compressible valve sleeve is substantially prevented. Newly presented claim 31 depends from claim 28 and recites that the valve mechanism further includes a valve sleeve seat for receiving the distal end of the compressible valve sleeve, and that the valve mechanism has a proximal end and a distal end, with the pinch member being proximal of the valve sleeve seat and the valve sleeve seat being proximal of the sheath receiver.


Reconsideration and reexamination are respectfully requested. It is respectfully submitted that all pending claims, namely claims 1-9, 11-15, 21 and 24-31, are now in condition for allowance. Issuance of a Notice of Allowance in due course is requested. If a telephone conference might be of assistance, please contact the undersigned attorney at (612) 677-9050.

Respectfully submitted,

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By their Attorney

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